K122897

510(k) Summary of Safety and Effectiveness
SENSE Head-Spine-Torso (HST) MR Coils

Submitted By:

Invivo Corporation
3545 SW 47th Avenue
Gainesville, FL 32608

DEC 2 1 2012

Date: December 20, 2012

Contact Person:

Lance Aulabaugh, Quality Engineer
Tel: (352) 336-0010, ext. 156 Fax: (352) 336-1410

Proprietary Name:

SENSE Head-Spine-Torso MR Coil System:
SENSE Spine 16
SENSE Head 16
SENSE Torso 16

Common Name: Coil, Magnetic Resonance, Specialty

Classification Name and Reference: 21 CFR 892.1000

A magnetic resonance diagnostic device, for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance, class II.

Device Product Code and Panel Code: MOS / Radiology / 90

Indications for Use:
The coils are indicated for use on the order of a physician, in conjunction with Philips 1.5T MR scanners as accessories to produce images of the head, spine and torso.

Device Description:
The **SENSE Head-Spine-Torso (HST) MR Coil System** includes 16 channel coil components that are designed for use with Philips 16-Channel 1.5T Magnetic Resonance Imaging (MRI) magnet systems. The coils work in unison with the Body Coil of the MRI system, which will transmit the radio frequency (RF) signals, so that the coils may receive the resultant RF signal from the excited nuclei. The coils are receive-only coils for high resolution imaging of thorax (including heart), abdomen, cervical, lumbar, and thoracic regions of the spine and the head, neck regions. The coils provide unilateral images of the anatomy of interest. The **SENSE HST** coils are designed to be used together and separately as follows:

Coil Models	Comments
Head + Spine + Torso	All three coils may be used together.
Head + Spine	Head Coil does not function unless it is connected to the Spine Coil.
Spine + Torso	Spine and Torso may be used together without the Head Coil
Spine	Spine Coil may be used alone.

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Substantial Equivalence Discussion:
When compared to the predicate devices, the SENSE Head-Spine-Torso system is substantially equivalent to the 1.5T 8-Channel Medium General Purpose Flex Coil (K093842, cleared March 5, 2010). Substantial equivalence is based on design rationale, safety features, magnet system compatibility and overall intended use. The indications for use statements differ with respect to the target anatomies; however, the predicate and new device system both fall within the same FDA class II product code, MOS and have the same fundamental intended use. Like the predicate, the proposed devices are receive-only MRI coils that are designed for use with Philips 1.5T magnet systems. The electrical isolation methods, decoupling method and housing material flammability ratings are the same for the predicate and new device.

	PREDICATE	NEW DEVICE
	1.5T 8-Channel Medium General Purpose Flex Coil K093842	SENSE Head-Spine-Torso System
Type of Device (FDA Product Code)	Accessory to MRI Scanner (MOS)	Accessory to MRI Scanner (MOS)
Indications for Use	The coil is indicated for use on the order of a physician, in conjunction with Philips 1.5T and 3.0T MR scanners as an accessory to produce images of the hip, knee, ankle, chest, and pelvic regions, as an aid to diagnosis.	The coils are indicated for use on the order of a physician, in conjunction with Philips 1.5T MR scanners as accessories to produce images of the head, spine and torso.
Target Anatomies	hip, knee, ankle, chest, and pelvic regions	head, spine and torso regions
System Compatibility	Philips 1.5T MRI Systems	Philips 1.5T MRI Systems
Type of Coil	Receive-Only	Receive-Only
Number of Channels	8 Channels	16 Channels
Decoupling Method	LC Tank Circuit	LC Tank Circuit
Electrical Isolation	Plastic housing with foam insulation	Plastic housing with foam insulation
Housing Materials & Flammability Rating	Polycarbonate Polyethylene Rating: UL94-HF-1	Polycarbonate Polyethylene Rating: UL94-HF-1
Type of MRI System Connector	Standard Multi-pin Connector	Standard Multi-pin Connector

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Summary of Non-Clinical Tests for Substantial Equivalency Determination:
Per Guidance for Industry: Guidance for the Submission of Premarket Notification for Magnetic Resonance Diagnostic Devices[1], the following preclinical testing was performed per the standards listed below and supports substantial equivalency to the predicate device: Signal to Noise Ratio (SNR)[2], Image Uniformity[3], Characterization of for Diagnostic MR Images[4] and IEC 60601 safety evaluation[5]. DICOM files from the 510(k) subject device were reviewed by a radiologist who confirmed the image quality is suitable for clinical applications.

Standards Referenced:

1. Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices Issued On November 14, 1998
2. NEMA Standards Publications MS 1-2008: *Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging*
3. NEMA Standards Publications MS 3-2008: *Determination of Image Uniformity in Diagnostic Magnetic Resonance Images*
4. NEMA Standards Publications MS 9-2008: *Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images*
5. IEC 60601 Standards:

IEC 60601-1, 1988; Amendment 1, 1991-11, Amendment 2, 1995.	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2: 2001 Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition:2001 consolidated with Amendment 1:2004)	Medical Electrical Equipment – Part 2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility—Requirements and Tests
IEC 60601-2-33: 2002 Amendment 1:2005	Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis

Substantial Equivalency Conclusion:
Based on a comparison of technological characteristics, conformance to safety standards preclinical test results, the SENSE Head-Spine-Torso MR coil system is substantially equivalent to the 1.5T 8-Channel Medium General Purpose Flex Coil cleared via K093842.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

INVIVO CORP
% Mr. Lance Aulabaugh
Quality Engineer
3545 SW 47th Avenue
Gainesville, FL 32608

Re: K122897
Trade/Device Name: SENSE Head-Spine-Torso MR Coil System:
SENSE Head 16
SENSE Spine 16
SENSE Torso 16
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: December 6, 2012
Received: December 7, 2012

Dear Mr. Aulabaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Indications for Use Form

510(k) Number (if known): K122897

Device Name: SENSE Head 16, SENSE Spine 16, SENSE Torso 16

Indications for Use: The coils are indicated for use on the order of a physician, in conjunction with Philips 1.5T MR scanners as accessories to produce images of the head, spine and torso.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Janine M. Morris -S
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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k): K122897